Claims 48 and 49 also find support on page 2, lines 1-23 of the specification, claim 50 finds support on page 4, lines 26-30, and claim 51 finds support on page 6, lines 19-34. These claims add no new matter, and Applicant respectfully requests their entry.

Claims 38-47 stand rejected under 35 USC §112, paragraph 1 and the judicially created doctrine of obviousness-type double patenting. Applicant thanks the Examiner for his thorough discussion of this case and co-pending case Serial No. 09/280,020 with the undersigned and Amylin Pharmaceuticals' attorney Molly Holman on October 5, 2001. The substantive issues discussed for both cases included the rejections of pending claims under §112, paragraph 1 and the judicially created doctrine of obviousness-type double patenting. Applicant thanks the Examiner for his indication of allowable subject matter. Applicant has amended the claims and included new claims directed to matter that the Examiner indicated would be allowable, and includes below discussion of the patentability of the rejected claims as amended herein.

The specification was objected to as not containing an abstract. Applicant encloses an abstract herewith. Support for the abstract can be found on page 4, lines 26-30. The abstract adds no new matter, and its entry is respectfully requested.

35 USC §112, paragraph 1

Claims 38-40 and 43-45 were rejected under §112, paragraph 1 as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventor had possession of the claimed invention at the time of filing. The Examiner alleges that Applicant's use of "agonist" broadens the claim language beyond the support in the specification. The Examiner further objects to the phrase "wherein said glucagon-like peptide 1 (7-36) amide agonist delays gastric emptying."

The Examiner's points are now moot in view of the amendments to the claims as discussed with the Examiner during the interview of October 5, 2001. Regarding the use of "agonist" in the claims, Applicant maintains that the terminology used in the specification is broader than the interpretation proffered by the Examiner, and supports the previous scope of the claims. However, in the interest of forwarding prosecution,

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Applicant has amended the claims and added new claims to conform to that matter which the Examiner indicated would be allowable. Applicant reserves the right to continue prosecution of broader claims in a continuation application.

For the foregoing reasons, Applicant respectfully requests that the Examiner withdraw his rejections of the claims under 35 USC §112.

Double Patenting Rejection

Upon an indication by the Office of allowable subject matter in this or the co-pending case Serial No. 09/280,020, Applicant will file a proper terminal disclaimer under 37 CFR 1.321(c) for the other case.

Applicant believes that the claims are in condition for allowance, and such action is respectfully requested. No fee is believed due, but if any fee should become due or credit become payable during the pendency of these proceedings, the Examiner is authorized to charge or credit the same to deposit account number 50-1273. If the Examiner believes that a prosecution could be forwarded by an interview, he is invited to call the undersigned at the number below.

Respectfully Submitted,

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MARKED COPY OF AMENDED PORTIONS OF THE SPECIFICATION

38. (Amended) A method of treating insulin-requiring [Type I] diabetes mellitus in a mammal comprising administering to said mammal an effective amount of

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an insulin and an effective amount of a glucagon-like peptide 1 (7-36) amide analogue, [agonist, wherein said glucagon-like peptide 1 (7-36) amide agonist delays gastric emptying and] wherein said glucagon-like peptide 1 (7-36) amide analogue [agonist] is administered subcutaneously.

39. A method according to claim 38 wherein said mammal is a human.

40. (Amended) A method according to claim 39 wherein said insulin and said glucagon-like peptide 1 (7-36) amide analogue [agonist] are administered to the human at a selected time prior to ingestion of a meal.

41. (Amended) A method according to any of claims 38-40 wherein said glucagon-like peptide 1 (7-36) amide analogue [agonist] is glucagon-like peptide 1 (7-36).

42. (Amended) A method according to any of claims 38-41 wherein said glucagon-like peptide 1 (7-36) amide analogue [agonist] is glucagon-like peptide 1 (7-37).

43. (Amended) A method of treating insulin-requiring [Type I] diabetes mellitus in a mammal comprising administering an effective amount of a glucagon-like peptide 1 (7-36) amide analogue, [agonist, wherein said glucagon-like peptide 1 (7-36) amide agonist delays gastric emptying and] wherein said glucagon-like peptide 1 (7-36) amide analogue [agonist] is administered subcutaneously.

44. (Amended) A method according to claim 43 [38] wherein said mammal is a human.

45. (Amended) A method according to claim 44 [39] wherein said glucagon-like peptide 1 (7-36) amide analogue [agonist] is administered to the human at a selected time prior to ingestion of a meal.

46. (Amended) A method according to any of claims 43-45 wherein said glucagon-like peptide 1 (7-36) amide analogue [agonist] is glucagon-like peptide 1 (7-37).

47. (Amended) A method according to any of claims 43-45 wherein said glucagon-like peptide 1 (7-36) amide analogue [agonist] is glucagon-like peptide 1 (7-36).

48. (New) A method of treating insulin-requiring diabetes in a mammal comprising administering subcutaneously to the mammal an effective amount of a peptide selected from the group consisting of

(a) glucagon-like peptide 1 (7-37);

(b) glucagon-like peptide 1 (7-36) amide; and

(c) an effective fragment or analogue of (a) or (b).

49. (New) The method of claim 48 further comprising administering an insulin.

50. (New) A method of treating insulin-requiring diabetes in a mammal comprising administering subcutaneously to the mammal an effective amount of a glucagon-like peptide 1-related peptide.

51. (New) The method of claim 50 further comprising administering an insulin.

52. (New) The method according to any of claims 38, 43, 48 and 50 wherein the insulin-requiring diabetes is Type I diabetes.

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Abstract

The present invention provides a method of treating insulin-requiring diabetes in a mammal comprising the subcutaneous administration of an effective amount of a glucagon-like peptide 1-related peptide.